between NCRR and the Sanctuary Contractor. A designated representative of the Secretary will monitor compliance. The responsibility to monitor compliance with the standards is delegated to NCRR/NIH/HHS. The NIH/NCRR Project Officer for this contract will conduct scheduled site visits at least one time annually (or more often if necessary) and review monthly and quarterly reports submitted to the Project and Contract Officer. Subcontractors are subjected to the same provisions. Failure to comply with the standards set forth in this part, or to correct deficiencies noted within the allowable time period, could result in termination of the contract by the Federal Government (HHS/NIH), or allow the Secretary to correct the deficiencies according to the terms and conditions outlined in the contract. The Secretary may impose additional sanctions on the contractor up to, and including, authorizing assumption or reassignment of the management of the sanctuary contract.

(b) *To what type of outside review or inspection will the federally supported sanctuary be subjected?* As noted in paragraph (a) of this section, the contractor for the sanctuary will be monitored on a regularly scheduled basis by representatives of NCRR/NIH/HHS. The NCRR representative will use facility site visits, reports, personal contact, and any other means as appropriate to ensure compliance with these standards. The contractor and subcontractors are required to obtain and maintain an Animal Welfare Assurance from NIH's Office of Laboratory Animal Welfare (OLAW) when chimpanzees are used for noninvasive studies as authorized in the CHIMP Act. In addition, the sanctuary must achieve accreditation by a nationally recognized animal program accrediting body (such as the AAALAC, the AZA, or similar recognized body) within a time frame to be determined by NCRR/NIH. The federally supported sanctuary must comply with the requirements set forth in the Animal Welfare Regulations (9 CFR parts 1 through 3).

§ 9.13 Other federal laws, regulations, and statutes that apply to the sanctuary.

(a) Animal Welfare Act (7 U.S.C. 2131–2159).

(b) Animal Welfare Regulations, 9 CFR, subchapter A, parts 1 and 2; part 3, subpart D—Specifications for the Humane Handling, Care, Treatment, and Transport of Nonhuman Primates.

PART 10—340B DRUG PRICING PROGRAM

Sec.

Subpart A—General Provisions

Subpart B—Eligibility To Purchase 340B Drugs

Subpart C—Drugs Eligible for Purchase under 340B

AUTHORITY: Sec. 340B of the Public Health Service Act (42 U.S.C. 256b), as amended; Sec. 215 of the Public Health Service Act (42 U.S.C. 216), as amended; Sec. 526 of the Federal Food, Drug, and Cosmetic Act, as amended (21 U.S.C. 360bb); Sec. 701(a) of the Federal Food, Drug, and Cosmetic Act, as amended (21 U.S.C. 371(a)); Sec. 1927 of the Social Security Act, as amended (42 U.S.C. 1396r–8).

SOURCE: 78 FR 44027, July 23, 2013, unless otherwise noted.

Subpart A—General Provisions

§ 10.1 Purpose.

This part implements section 340B of the Public Health Service Act (PHSA) ''Limitation on Prices of Drugs Purchased by Covered Entities.''

§ 10.2 Summary of 340B Drug Pricing Program.

Section 340B of the PHSA instructs the Secretary of Health and Human Services to enter into agreements with

manufacturers of covered drugs under which the amount required to be paid to these manufacturers by certain statutorily-defined entities does not exceed the average manufacturer price for the drug under title XIX of the Social Security Act (SSA) reduced by a rebate percentage which is calculated as indicated in 340B(a)(1) and 340B(a)(2)(A). Manufacturers participating in the 340B Drug Pricing Program (340B Program) are required to provide these discounts on all covered outpatient drugs sold to participating 340B covered entities.

§ 10.3 Definitions.

Ceiling price means the maximum statutory price established under section 340B(a)(1) of the PHSA.

Covered entity means an entity that meets the requirements under section 340B(a)(5) of the PHSA and is listed in section 340B(a)(4) of the PHSA.

Covered outpatient drug has the meaning set forth in section 1927(k) of the SSA.

Group purchasing organization (GPO) is an entity that contracts with purchasers, such as hospitals, nursing homes, and home health agencies, to aggregate purchasing volume and negotiate final prices with manufacturers, distributors, and other vendors.

Manufacturer has the same meaning as set forth in section 1927(k)(5) of the SSA.

Orphan drug means a drug designated by the Secretary under section 526 of the Federal Food, Drug, and Cosmetic Act (FFDCA).

Participating drug manufacturer means a manufacturer that has entered into a Pharmaceutical Pricing Agreement with the Secretary.

Pharmaceutical Pricing Agreement (PPA) means an agreement described in section 340B(a)(1) of the PHSA.

Secretary means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

Section 340B means section 340B of the PHSA.

Subpart B—Eligibility To Purchase 340B Drugs

§ 10.10 Entities eligible to participate in the 340B Drug Pricing Program.

Only organizations meeting the definition of a covered entity and listed on the 340B database are eligible to purchase covered outpatient drugs under the 340B Program. A covered entity remains responsible for complying with all other 340B requirements and applicable Federal, state, and local laws.

Subpart C—Drugs Eligible for Purchase Under 340B

§ 10.20 Drugs eligible for purchase under 340B.

The definition of a covered outpatient drug has the meaning given to such term in section 1927(k)(2) of the SSA except as provided in § 10.21 of this part.

§ 10.21 Exclusion of orphan drugs for certain covered entities.

(a) *General.* For the covered entities described in paragraph (b) of this section, a covered outpatient drug does not include orphan drugs that are transferred, prescribed, sold, or otherwise used for the rare condition or disease for which that orphan drug was designated under section 526 of the FFDCA. A covered outpatient drug includes drugs that are designated under section 526 of the FFDCA when they are transferred, prescribed, sold, or otherwise used for any medically-accepted indication other than treating the rare disease or condition for which the drug was designated under section 526 of the FFDCA.

(b) *Covered entities to which the orphan drug exclusion applies.* (1) The exclusion of orphan drugs when used to treat the rare disease or condition for which the drug was designated under section 526 of the FFDCA from the definition of covered outpatient drugs described in paragraph (a) of this section shall only apply to the following covered entities: free-standing cancer hospitals qualifying under section 340B(a)(4)(M) of the PHSA, critical access hospitals qualifying under section 340B(a)(4)(N) of the PHSA, and rural referral centers and sole community hospitals qualifying

under section 340B(a)(4)(O) of the PHSA. The exclusion does not apply to the remaining covered entities that meet the 340B Program eligibility requirements.

(2) When an entity described in this paragraph (b) meets more than one eligibility criterion as a covered entity, the entity shall select its eligibility type and notify the Secretary. These eligible entities are limited to participating in the 340B Program under only one covered entity hospital type and shall abide by all applicable restrictions and requirements for that entity type. A covered entity subject to this provision may only change its participation type to another hospital entity type on a quarterly basis upon express written confirmation from the Secretary.

(c) *Covered entity responsibility to maintain records of compliance.* (1) A covered entity listed in paragraph (b) of this section is responsible for ensuring that any orphan drugs purchased through the 340B Program are not transferred, prescribed, sold, or otherwise used for the rare condition or disease for which the orphan drugs are designated under section 526 of the FFDCA. A covered entity listed in paragraph (b) of this section that purchases orphan drugs under the 340B Program is required to maintain and provide auditable records on request which document the covered entity's compliance with this requirement available for audit by the Federal Government or, with Federal Government approval, by the manufacturer.

(2) A covered entity may develop an alternative system by which it can prove compliance. Any alternate system must be approved by the Secretary prior to implementation. Each alternate system of compliance will be reviewed on a case-by-case basis.

(3) A covered entity listed in paragraph (b) of this section that cannot or does not wish to maintain auditable records sufficient to demonstrate compliance with this rule, must notify HRSA and purchase all orphan drugs outside of the 340B Program regardless of the indication for which the drug is used. Once a hospital is enrolled in 340B, it may change its decision to purchase all orphan drugs outside of the 340B Program on a quarterly basis by notifying HRSA.

This documentation will be made public. This information will also be verified during the annual recertification process.

(d) *Use of group purchasing organizations by a free-standing cancer hospital.* (1) A free-standing cancer hospital enrolled under section 340B(a)(4)(M) must also comply with the prohibition against using a GPO under section 340B(a)(4)(L)(iii) of the PHSA for the purchase of any covered outpatient drug.

(2) A covered entity that is a free-standing cancer hospital cannot use a GPO to purchase orphan drugs when they are transferred, prescribed, sold, or otherwise used for an indication other than the rare condition or disease for which that orphan drug was designated under section 526 of the FFDCA.

(3) A covered entity that is a free-standing cancer hospital may use a GPO for purchasing orphan drugs when orphan drugs are transferred, prescribed, sold, or otherwise used for the rare disease or condition for which it was designated under section 526 of the FFDCA.

(4) If a covered entity that is a free-standing cancer hospital chooses to use a GPO for purchasing an orphan drug used for a rare disease or condition for which it is designated, it is required to maintain auditable records that demonstrate full compliance with the orphan drug purchasing requirements and limitations. A free-standing cancer hospital covered entity that cannot or does not wish to maintain auditable records sufficient to demonstrate compliance, must notify HRSA and purchase all orphan drugs outside of the 340B Program, regardless of indication for which the drug is used, and is not permitted to use a GPO to purchase those drugs. Once a free-standing cancer hospital is enrolled in 340B, it may change its decision to purchase all orphan drugs outside of the 340B Program on a quarterly basis by notifying HRSA. This documentation will be made public. This information will also be verified during the annual recertification process.

(e) *Identification of orphan drugs.* Designations under section 526 of the FFDCA are the responsibility of and administered by the FDA. Only covered outpatient drugs that match the listing and sponsor of the orphan designation are considered orphan drugs for purposes of this section. HRSA will publish on its public Web site FDA's section 526 list of drugs that will govern the next quarter's purchases.

(f) *Failure to comply.* Failure to comply with this section shall be considered a violation of sections 340B(a)(5) and 340B(e) of the PHSA, as applicable.